Section 5

Catheter Repair Kit with Replacement Connector
510(k)

Summary of Safety and Effectiveness Information
21 CFR 807.92

1. Submitter Information:

Submitter Name:	Bard Access Systems, Inc. [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5525
Fax Number:	(801) 595 5425
Contact Person:	Glenn Norton
Date of Preparation:	February 10, 2003

2. Device Name:

Device Name:	Catheter Repair Kit with Replacement Connector
Trade Name:	Catheter Repair Kit
Common/Usual Name:	Catheter Repair Kit
Classification Name:	MSD Blood Access Device Accessory 21 CFR 876.5540 Class II
Classification Panel:	Gastroenterology and Renal

3. Predicate Device Name:

Device Name:	Catheter Repair Kit with Replacement Connector
Trade Name:	Catheter Repair Kit
Common/Usual Name:	Catheter Repair Kit
Classification Name:	MSD Blood Access Device Accessory 21 CFR 876.5540, Class II
Classification Panel:	Gastroenterology and Renal

4. Device Description

The Catheter Repair Kit with Replacement Connector is exactly the same as the predicate device.

5. Intended Use

To replace: Cracked or broken female luer lock connectors or repair damaged extension leg where there is a minimum of 4.5 cm of viable extension tubing on the following catheters:

- Soft-Cell® Long-Term Dual Lumen Catheter
- Opti-Flow® Long-Term Dual Lumen Catheter
- Slim-Cath™ Short-Term Dual Lumen Catheter
- Vaccess® Short-Term Single Lumen Catheter
- Flexxicon® Short-Term Dual Lumen Catheter
- Niagara™ Short-Term Dual Lumen Catheter
- Flexxicon® II Short-Term Dual Lumen Catheter
- HemoGlide™ Long-Term Dual Lumen Catheter
- HemoSplit™ Long-Term Hemodialysis Catheter

6. **Technological Characteristics Summary:**

6.1 Does the new device have the same indication statement?

No. A change to the indications is the subject of this submission. The change includes removal of the generic Vas-Cath® trade name and the addition of the trade name HemoSplit™ to the list of repairable catheters.

6.2 Do the differences alter the intended therapeutic/diagnostic/etc. effect? Deciding may consider impact on safety and effectiveness.

No, the intended use is the same. There is only the addition of a catheter trade name to the list of repairable catheters.

6.3 The new device has the same intended use and may be "Substantially Equivalent."

Yes, the intended use is identical.

6.4 Does the new device have the same technological characteristics, e.g. design, materials, etc.?

Yes, the technological characteristics are exactly the same.

6.5 Are the descriptive characteristics precise enough to ensure equivalence?

Yes.

Conclusion:

Based on FDA's decision tree, the Catheter Repair Kit with Replacement Connector is substantially equivalent to the predicate device, Catheter Repair Kit with Replacement Connector, K022561, concurrence date January 23, 2002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Mr. Glenn Norton
Sr. Regulatory Affairs Specialist
Bard Access Systems, Inc.
C. R. Bard, Inc.
5425 W. Amelia Earhart Drive
SALT LAKE CITY UT 84116

Re: K030442
Trade/Device Name: Catheter Repair Kit with Replacement Connector – (adding the HemoSplit® Catheter, 14.5 F x 19cm curved and 42 cm straight)
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 NFK
Dated: June 27, 2003
Received: June 30, 2003

Dear Mr. Norton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K030442

Section 1-D

Catheter Repair Kit with Replacement Connector

510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the following device, Catheter Repair Kits with Replacement Connectors, is indicated for the following:

To replace: Cracked or broken female luer lock connectors or repair damaged extension where there is a minimum of 4.5 cm of viable extension tubing on the following catheters: Soft-Cell® Long-Term Dual Lumen Catheter, Opti-Flow® Long-Term Dual Lumen Catheter, Slim-Cath™ Short-Term Dual Lumen Catheter, Vaccess® Short-Term Single Lumen Catheter, Flexxicon® Short-Term Dual Lumen Catheter, Niagara™ Short-Term Dual Lumen Catheter, Flexxicon® II Short-Term Dual Lumen Catheter, HemoGlide™ Long-Term Dual Lumen Catheter, and HemoSplit™ Long-Term Hemodialysis Catheter.

Signature of 510(k) Submitter: _____

Printed Name of Submitter: Glenn Norton

Date: 2·10·2003

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

510(k) Number _____

Division Sign-Off
Office of Device Evaluation _____

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030442